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Docket No. G-045US02PCT
Serial No. 09/744,527Remarks

Claims 1, 10, 15, 21, 24-28, 32, and 39-81 were pending in the subject application. By this Amendment, claim 43 has been amended and claims 1-42 and 77 canceled. Accordingly, claims 43-76, and 78-81 are currently before the Examiner for consideration. Applicants have amended the currently pending independent claim to include the limitations found in previously pending, and examined, claim 77 in order to advance various business interests and to advance prosecution. Accordingly, it is respectfully submitted that the currently presented claims would not require a new search, require new consideration, or raise new issues on the part of the Patent Office. Additionally, it is respectfully submitted that entry of the instant amendment would simplify issues remaining in this application. Entry and favorable consideration of the pending claims is respectfully requested.

It is noted that the Office Action indicates that claims 80-81 are directed to an invention that is independent or distinct from the invention originally claimed. However, Applicants again respectfully request that any requirement to cancel claims not currently under examination be held in abeyance in order to allow for the rejoinder of claims directed to methods of making and/or using the compositions claimed herein in light of Patent Office policy related to the treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b) at such time as the composition claims currently pending are found allowable.

Claims 69-76 and 78-79 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the invention was made, had possession of the claimed invention. The Office Action asserts that the specification fails to contain a sufficient disclosure of the structure and function of all GGPPSASE fragments or portions of SEQ ID NO:4. While Applicants maintain that the as-filed specification adequately describes the claimed subject matter, it is respectfully submitted that this rejection is moot in view of the amendment of claim 43 to incorporate the limitations of claim 77 (a claim not rejected under this section of Title 35) into the independent claim. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 69-76 and 78-79 have been rejected under 35 U.S.C. §112, first paragraph, because the specification, while enabling for the GGPPSASE of SEQ ID NO: 4, does not reasonably provide enablement for fragments of SEQ ID NO: 4 of unknown structure or function. Again, while

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Applicants respectfully disagree with the position of the Patent Office in this regard, the claims have been amended to provide a recitation of claim 77 in the base claim thereby rendering this rejection moot.

Claims 43-76 and 78-79 have been rejected under 35 U.S.C. §112, second paragraph, because the mere recitation of the name hGGPPS is insufficient to convey with clarity that which application sees as the invention. Applicants respectfully submit that acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. In the case of the instant application, it is respectfully submitted that one of ordinary skill in the art would understand (in light of the specification) that hGGPPS was human geranylgeranyl pyrophosphate synthetase. However, Applicants have amended claim 43 to indicate that hGGPPS is human geranylgeranyl pyrophosphate synthetase (hGGPPS) in the interest of advancing prosecution in this matter; accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 43-79 have been rejected under 35 U.S.C. §102(e) as being anticipated by Greene et al. (U.S. Patent No. 5,786,193) or under 35 U.S.C. § 102(b) as being anticipated by Greene et al. (WO 96/21736). The Office Action argues that the references teach fragments and portions of a GGPPS polypeptide and that a truncated polypeptide is one that is a part broken off of the wildtype, detached, or incomplete, which can be construed as a fragment or variant of the wildtype, modified by deletion. Applicants again respectfully traverse.

It is well settled law that a claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The Office Action asserts that the prior art reference teaches fragments of the hGGPPS polypeptide (pointing to pages 9-10 of the '736 patent application and columns 6-7 of the '193 patent). The Office Action also references Figure 3 of both references. Applicants respectfully submit that the passages pointed to in the cited prior art references fail to disclose subject matter that anticipates the claimed invention. For example, the '193 patent discloses fragments of Figure 1 (SEQ ID NO.2). As recited in the specification of the '193 patent (at column 6, lines 19-33) and the paragraph bridging pages 9-10 of the '736 application:

The fragment, derivative or analog of the polypeptide of FIG. 1 (SEQ ID No. 2)

or that encoded by the deposited cDNA may be (i) one in which one or more of the

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amino acid residues are substituted with a conserved or non-conserved amino acid residue (preferably a conserved amino acid residue) and such substituted amino acid residue may or may not be one encoded by the genetic code, or (ii) one in which one or more of the amino acid residues includes a substituent group, or (iii) one in which the mature polypeptide is fused with another compound, such as a compound to increase the half-life of the polypeptide (for example, polyethylene glycol). Such fragments, derivatives and analogs are deemed to be within the scope of those skilled in the art from the teachings herein.

As is apparent from this passage, the cited references only disclose fragments of Figure 1 (SEQ ID NO: 2). A review of the sequences provided for Figure 1 and SEQ ID NO: 2 indicates the following amino acids at positions 204, 205, 225, and 295: 204 = Leu; 205 = Gly; 225 = Ser; and 295 = Ser. These amino acids differ from those claimed in the instant application where the truncated polypeptide contains a contiguous span that includes at least one amino acid selected from the group consisting of: a.) a Phe residue at position 204 of SEQ ID NO:4; b.) a Phe residue at position 295 of SEQ ID NO:4; c.) a Cys residue at position 205 of SEQ ID NO:4; and d.) a Pro residue at position 225 of SEQ ID NO:4. While Applicants note that the Office Action points to Figure 3 in support of the rejection of record, it is respectfully submitted that both references fail to mention or disclose fragments of the polypeptide of Figure 3. Rather, the portions of the documents pointed to in the Office Action discuss the polypeptide disclosed in Figure 1 and SEQ ID NO: 2. Thus, it is respectfully submitted that the reference fails to teach truncated polypeptides containing the required amino acids at the positions recited in the claims and that the references fail to anticipate the claimed invention. It is further submitted that the cited prior art fails to teach truncated polypeptide wherein the contiguous span consists of: a) 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, or 100 amino acids; or b) amino acid positions 200 through 300 of SEQ ID NO: 4 (see claims 71-76 and 79). Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

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The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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